



**3rd
GENERAL DRAFT STANDARD
FOR BOTTLED
FLAVOURED WATER
BY IHWF INDIA**

GENERAL DRAFT STANDARD FOR BOTTLED/ FLAVOURED WATER (NON-SWEETENED)

1. SCOPE

This Standard applies to Flavoured water that are prepackaged / bottled and are suitable for human consumption.

2. DESCRIPTION

2.1 Flavored Water~ Shall mean *Prepared water containing *#Natural Flavours or **Nature identical Flavouring Substances not more than #0.05% derived from extracts of Herbs, Fruits or parts of Plant origin, flavor concentrates (permitted food additive substances as Carryover in 14.1.1 FSSR / Codex GSFA /GMP) in minute traces, either singly or in combination. It contains No color, no more of flavor No sweeteners, No Carbonated gas, No calories. It gives Calories 0, Total fat 0g, Saturated fat 0g, Trans fat 0g, Total carbs 0g, Sugars 0g, Protein 0g.

2.2 Flavored Water - Water filled into hermetically sealed containers of various compositions, forms, and capacities that is safe and suitable for direct consumption without necessary further treatment. Flavored Water is considered a food. The terms "Prepared water" are used interchangeably in relation to water.

2.3 Flavoured water intended for bottling should be such (i.e. microbiologically, chemically, physically, and radiologically), that treatment if necessary (including multiple barrier treatments such as combination of filtration, chemical disinfection, with add food additive (Flavor) etc.) of that water during processing results in finished Flavoured water products that are safe and suitable for consumption and should comply with standard before going to market.

*#Natural Flavors extract prepared Definition: ((liquid or solid)) for water-based flavoured drinks flavoured water (unsweetened) Natural /Flavor/Extract /Oleoresin/ essential oils /distilled/ essence or extractive are created from natural aromatic herbs / vegetable / fruit /flower/or spice as a dried seed, root, and bark or entire plant can be eaten raw as sources with permitted food additive substances as Carryover in 14.1.1 Codex GSFA /GMP

**Nature-Identical Flavors extract prepared Definition: ((liquid or solid)) for water-based flavoured drinks flavoured water (unsweetened) Natural /Flavor/Extract /Oleoresin/ essential oils /distilled/ essence or extractive are created from natural aromatic herbs / vegetable / fruit /flower/or spice as a dried seed, root, and bark or entire plant can be eaten raw as sources with permitted food additive substances as Carryover in 14.1.1 Codex GSFA /GMP

Recommended Max Level as per committee decision and not as a standard under regulations of Flavor Concentrates to be used in flavoured water (unsweetened) in (0.05%) w/w = 500 ppm

2.4 **“Unprocessed Waters defined”**

2.5 Unprocessed Waters can be drawn from tube well (borewell); protected well, or drinking water systems - Public or private systems providing the consumer with tap water safe and suitable for direct consumption and can be brought from other place through a protected container to process Prepared water as industrial raw material

2.6 Unprocessed Waters should not be taken from potential sources of underground contamination, such as sewers, septic tanks, industrial waste ponds, gas or chemical tanks, pipelines and solid waste disposal sites.

2.7 When storage and transport of the water intended for bottling from the point of origin to the processing plant is necessary, these operations must be conducted in a hygienic manner to prevent any contamination. To follow Schedule 4 of FSS Regulation, 2011 from time to time

2.8 Unprocessed treatment plant samples should be collected from the inlet and outlet for monitoring of the different stages of water treatment, sampling should take place before and after the respective stage being monitored **see Q1 chart**

2.9 **Points to be considered for Basic Design of Flavoured Water Equipment**

a The principal water system design should be predetermined on maximum momentary water flow rate, application time and frequency of water to be used, and such conditions demanded at the points of use as temperature, number of ports, and piping specifications, including branches and pipes' diameters.

b The locational adequacy of water sampling ports for water quality control should be evaluated so well as to ensure stable supply of Flavoured water that fulfill required quality specifications.

c Water samples should be collected from the locations not only of points of use but also at other critical points for the Flavoured water process. Locations necessary for water quality assessment should be provided with certain structural features that facilitate the sampling for quality analysis. If no sampling ports can structurally be set up at the expected locations, the ports should preferably be located as close to the points of use as possible.

d Materials used for Flavoured water equipment should be selected so suitably as to maintain and control water quality at the required level. In particular, such corrosion-resistant materials as stainless steel 304/316/316L grade should be selected and should have smooth surfaces given especially at the locations contacting water

- E Pretreatment equipment should be selected in consideration of the capacity suitable for maintaining invariable water quality within the specifications required and for maximizing water treatment efficiency and system life on the basis of elaborate investigation of the amounts of heavy metals, free chlorine, organic matter, micro organisms, and colloidal particles, etc. present in the source water
- F The reverse osmosis (RO) is used to improve various factors in water quality by allowing water to flow through permeable and semi-permeable membranes based on osmotic pressure differentials to remove small molecular solutes similar in size to inorganic salts as well as solvent molecules, micro organisms, endotoxins etc. depending on their respective concentrations in source water. Although RO can be treated at an ambient temperature and its performance is highly cost effective in energy-saving compared with distillation, stricter control than that of distillation is required to prevent any leaks due to pinholes into the downstream and microbial contamination.
- G Points to consider in designing RO membrane units are shown below:
- H As no gaseous carbon dioxide and ammonia can be removed from feed water by RO, such prior pretreatment as desecration, neutralization, and/or ion-exchange should be required on occasional demand.
- I Appropriate equipment for the microbiological control and monitoring should be included in place in the pretreatment system for feed water to meet the predetermined control criteria.
- J As RO generally operated at an ambient temperature may cause some concern about downstream contamination due to leaks through pinholes developed in the membrane, the structural system composed of two ROs in series should preferentially be designed to provide enhanced reliability and better control.
- K Additionally, UV sterilization, heat-sterilization, and other appropriate treatments in the downstream should be performed to inhibit microbial growth in the system.

2.10 ***Prepared water (food ingredients)**

Prepared water used as (safe food ingredients) with any food preparation, Prepared water cannot be sold as such singly, Prepared water is a industrial raw material it will be labeled as one of ingredients in any food product,

3 Carry over Food Additives

3.1 Carryover of Food Additives - For the purpose of this standards the "Carry Over" principle applies to the presence of additives such as colours, flavouring agents, anti-oxidants, emulsifying and stabilizing agents and preservatives in food, as a result of the use of raw material or other ingredients in which these additives were used. The presence of contaminants is not covered by this purpose. (as per 3.1.18: Carry over of food additives food safety and standards (food products standards and food additives) regulations, 2011)

4. Essential Composition and Quality Factors for Flavoured water

Basic Ingredients

4.1 Prepared water (food ingredients) 99.95 %

4.2 *#Natural Flavours or **Nature identical Flavouring Substances not more than #0.05%

4.3 Permitted food additive substances as Carryover in 14.1.1 FSSR / Codex GSFA /GMP

5. Quality Factors for Water-Based Beverage Flavoured Water. Essential quality norms for Flavoured Water:

5.1 All the food additive should comply with respective standards as per food safety and standards (food products standards and food additives) regulations, 2011

5.2 Contents of food additive should be safe for human consumption and health as per food safety and standards (food products standards and food additives) regulations, 2011

5.3 The product should be free from abnormal odour, foreign matters, insects and part of them as per food safety and standards (food products standards and food additives) regulations, 2011

6. Preservatives Used For Concentrates, Extracts, Condensation. Preservatives may be added for one or more of the following purposes:

6.1 Carry over food additives (preservative) approved under food safety and standards (food products standards and food additives) regulations, 2011

6.2 Preservative should be a food grade substance for use in Flavour extracts.

6.3 To retain the flavour Concentrate, Extract, Condensation properties in good condition.

6.4 To retain quality, stability and to enhance shelf life.

6.5 To add or enhance taste to Flavoured Water.

- 6.6 To process Flavoured Water, to retain water quality properties during manufacture, packaging and transport.
- 6.7 To provide essential constituents of Flavoured drinking water; which complies with applicable of purity or quality in respect of flavour used.
- 6.8 Preservative shall not be directly added to Flavoured water. Carry over food additives will apply (Permitted food additive substances as Carryover in 14.1.1 FSSR / Codex GSFA /GMP)

7. Types of Flavoured Water.

- 7.1 Flavoured Water.
- 7.2 Sweetened Flavoured Water As per 2.1: Packaging Food Safety and Standards (Packaging and Labelling) Regulations, 2011

8. Requirements for Flavoured Water.

- 8.1 Hygienic conditions, Flavour Enriched Water processed in factories maintained in accordance with Schedule 4 of FSS Regulation, 2011
- 8.2 Flavour concentrates / extract or Condensation, Flavour should be procured with Certificate of analysis. Flavour extracts should be with batch no, date of manufacture and expiry

9. Product Durability.

- 9.1 Product durability shall be declared on package. Product durability should be declared considering shelf life, adequate shelf life studies to be conducted, laboratory results and other examinations. Quality and Analysis checks needs to be done on batch basis and records should be maintained.

10. Packing Containers.

- 10.1 The Flavoured Water shall be properly packed in clean glass bottles, colored bottles, food grade plastic containers PET /PC / HDPE/ LDPE, Aluminum Cans. As per 2.1: Packaging Food Safety and Standards (Packaging and Labelling) Regulations, 2011
- 10.2 All Flavoured Water refills shall be cleaned and sanitized using latest technology and Good Manufacturing Practice (GMP)
- 10.3 The containers shall be filled in hygienic atmosphere. GMP needs to be followed

- 10.4 Inspection of Empty and Filled Containers (**See FSMS**)
- 10.5 Containers shall be inspected thoroughly before and after filling. Bright light can be used in back ground to check containers. Magnification boxes may be used if necessary. Defective containers and product contained should be rejected. (Given in IHWF - FSMS)

11. Weights and measures.

- 11.1 Standard of Weights & Measures (Packaged Commodities) Rules, 1977 may also be followed for deciding packing size and also considered for designing standard.

12. Labeling.

- 12.1 Labels should follow all applicable regulations as per Food Safety and Standards (Packaging and Labelling) Regulations, 2011. The following information should be given on label/ container.
- 12.2 The information should be legible:
- 12.3 Brand Name;
- 12.4 Category (Flavoured Water) Water-based beverages
- 12.5 Ingredients; (Prepared water; Herbs; Fruits or parts of Plant origin extracts; Flavour name shall be used or approved food additive)
- 12.6 Name and address of Manufacturer
- 12.7 Marketing office address where required;
- 12.8 Date of manufacture;
- 12.9 Batch number;
- 12.10 Net volume of content;
- 12.11 Condition for storage;
- 12.12 Classes names, if any;
- 12.13 Best before use;
- 12.14 Not for medical use;
- 12.15 Nutritional Facts;
- 12.16 Once opened use before;
- 12.17 Pictorial representation indicating Flavoured Water;
- 12.18 Processing methods;
- 12.19 Country of origin;
- 12.20 Crush the bottle after use; (If it's one time use Container)
- 12.21 Preservatives; Carry over food additives (Permitted food additive substances as Carryover in 14.1.1 FSSR / Codex GSFA /GMP) apply
- 12.22 Any other markings required under The Legal Metrology (Packaged Commodities) Rules, 2011.

13. Sampling for testing.

13.1 Samples to be collected to test microbiological/chemical/quality tests when production is done in batches constituting lots, samples of each lot needs to be maintained with details of production batch details. Samples from each lot will be tested to conform to required quality standards. Samples need to be collected on random basis. Samples should be suitably numbered.

14. Testing.

Internationally accepted testing methods should be followed. However Standards for Prepared water shall apply since major ingredient is water. Other tests to confirm property of Herbs, Fruits or parts of Plant origin extracts value needs to be done. Ingredient property testing should be done using HPLC, TLC, UV Visible Spectrometer, Titration Method and Colour test etc. applied.

15. Qualities of Testing Reagents.

Only pure chemical, which does not contain impurities, pure should be used for testing since Quality of Chemicals used influence test results largely. Double Distilled water should be used when required.

16.

Draft Standard for Flavoured water (Non – sweetened)

Parameters (14.1.1.2)	Flavoured water mg/kg Max	JECFA Evaluation (Monograph link)	Method of test
(Physical)			
Colour (TCU)	2		3025 (Part 4)
Odour	Agreeable		3025 (Part 5)
*#; **; #Flavor (mg/l)	500		Macroscopy/Microscopy/TLC/HPLC/
Taste	Agreeable		3025 (Part 7 & 8)
Turbidity (NTU)	2		3025 (Part 10)
TDS (mg/l)	500		3025 (Part 16)
pH	6.5-8.5		3025 (Part 11)
Total Hardness (mg/l)	No guideline		3025 (Part 21)
Residual Free Chlorine	0.2		3026 (Part 26)
Nitrate (N),(mg/l)	45	NITRATE	3025 (Part 34) / ISO 10304-1:2007/ ISO 13395:1996/ISO 7890-3:1988
Nitrite (NO2),(mg/l)	0.02	NITRITE	3025 (Part 34) / ISO 10304-1:2007/ ISO13395:1996/ISO 6777:1984
Sulphide (as H2S), ,(mg/l)	0.05		3025 (Part 29)
Manganese (Mn),(mg/l)	0.1		IS 3025 (Part 59) ISO 11885:2007 ISO 17294-2:2003 ISO 15586:2003 ISO 8288:1986/ EPA 200.8
Copper (Cu),(mg/l)	0.5	COPPER	3025 (Part 42) / ISO 11885:2007 ISO 17294-2:2003 ISO 15586:2003 ISO 8288:1986/ EPA 200.8
Zinc ,(mg/l)	5	ZINC	3025 (Part 49)
Fluoride (F),(mg/l)	1		3026 (Part 60) ISO 10304-1:2007 ISO 10359-1:1992 (dissolved Fluoride) ISO 10359-2:1994 (inorganic bound)

Barium (Ba),(mg/l)	0.7		IS 13428/IS 15302 / ISO 11885:2007/ ISO 17294-2:2003/EPA 200.8
Antimnony (Sb),(mg/l)	0.005		ISO 17294-2:2003 ISO 15586:2003 EPA 200.8
Borate (B),(mg/l)	5		IS 13428 /ISO 9390:1990/ ISO 11885:2007/ ISO 17294-2:2003
Silver (Ag),(mg/l)	0.1	SILVER	IS 13428
Chloride,(mg/l)	200		3025 (Part 32) / AOAC 973.51 / ISO 9297:1989 (confirmed 1994)
Sulphate (as SO4),(mg/l)	200		3025 (Part 24) / ISO 9280:1990
Magnesium (as Mg),	30		3025 (Part 46) / ISO 6059:1984 ISO 7980:1986
Molybdenum (as Mo),(mg/l)	0.07		3025 (Part 2;2002) / ISO 11885: 1996
Calcium (as Ca) , ,(mg/l)	75		3025 (Part 40) / ISO 7980:1986
Sodium,(mg/l)	200		IS 3025 (Part 45)
Alkalinity as CaCO ₃	200 as HCO ₃		3025 (Part 23)
Selenium (Se),(mg/l)	0.01		IS 15303 /ISO 17294-2:2003 ISO 15586:2003/ ISO 9965:1993/EPA 200.8
Mineral Oil	Absent	Mineral Oil	IS 3025 (Part 39) ISO 9377-2:2000
Phelonic Compounds (as C ₆ H ₅ OH) ,(mg/l)	Absent		3025 (Part 43) / ISO 6439:1990
Anionic Surfactants	0.2		IS 13428
Boron,(as B)(mg/l)	2.4		IS 3025 (Part 57)
Iron,(mg/l) 0.3	IRON		3025 (Part 53) / ISO 6332:1988
Aluminium,(mg/l)	0.02	ALUMINIUM	3025 (Part 55)
Mercury (Hg),(mg/l)	0.001	MERCURY	IS 3025 (Part 48) / EN 1483:2007 ISO 117852:2006/ISO 5666-:1999 ISO 16590:2000//EPA 200.8

Cadmium (Cd),(mg/l)	0.003	CADMIUM	IS 3025 (Part 41) ISO 11885:2007/ ISO 17294-2:2003 ISO 15586:2003/ ISO 5961:1994 (Section 3)/EPA 200.8
Arsenic (As),(mg/l)	0.01	ARSENIC	IS 3025 (Part 37) ISO 17294-2:2003 ISO 15586:2003/ ISO 11969:1996/EPA 200.8
Cyanide (Cn),(mg/l)	0.05		IS 3025 (Part 27) ISO 14403:2002 ISO 6703-1:1998
Lead (Pb),(mg/l)	0.01	LEAD	IS 3025 (Part 47) ISO 17294-2:2003 ISO 15586:2003/ EPA 200.8
Chromium (Cr),(mg/l)	0.05		IS 3025 (Part 52) ISO 11885:2007 ISO 17294-2:2003 ISO 15586:2003 ISO 18412:2005 (Cr VI)/ ISO 23913:2006 (Cr VI)/ ISO 9174:1998 (Section 4) EPA 200.8
Nickel (Ni),(mg/l)	0.02		IS 3025 (Part 54) ISO 17294-2:2003 ISO 15586:2003/EPA 200.8
Polychlorinated biphenyle (PCBs)	ND		ASTM 5175/ APHA 6630 AOAC 990.06
Polynuclear Aromatic Hydrocarbons (PAH)	0.0001		APHA 6440 / ISO 17993:2004 ISO 7981-1:2005/ISO 7981-2:2005
Acrylamide	0.0005	ACRYLAMIDE	

Microbiological Limits

Faecal Streptococci in 250ml/CFU	Absent	IS 5887 (Part 2) / IS 15186 / ISO 7899-2:1984
Staphylococcus aureus	Absent	IS 5887 (Part 2) / IS 15186 / ISO 7899-2:1984
Sulphite reducing anaerobes	Absent	IS 13428 /ISO 9308-1:1990
Escherichia coli,250 ml	Absent	IS 5887 (Pt 1)/IS 15185
Pseudomonas aeruginosa ,250 ml	Absent	IS 13428 /(ISO 8360/2)
Aerobic microbial count –37°C in 24hrs on agar agar gel	20	IS 5402
Aerobial microbial plate count –20°C in 72hrs on agar	100	IS 5403
Yeast and moulds in 250 ml	Absent	IS 5403
Salmonella in 250 ml	Absent	IS 5887(Part 3) /IS 5887 (Pt 7) IS 15187
Shingella in 250 ml	Absent	IS 5887(Part 3) /IS 5887 (Pt 7) IS 15187
Vibrio Cholerae in 250 ml	Absent	IS 5887 (Part 5)
Vibrio parahaemolyticus in 250 ml	Absent	IS 5887 (Part 5)
Total Aflatoxin (B1+B2+G1+G2)	20 µg/kg (ppb)	EN /ISO/ AOAC/ASTA/USP
Aflatoxin B1	5 µg/kg (ppb)	EN /ISO/ AOAC/ASTA/USP
Patulin	50 µg/kg	EN /ISO/ AOAC/ASTA/USP

Nutritional information

Fat	0%	Pearson's Composition and Analysis of Food 9th Edition 1991
Protein (N x 6.5)	0%	Pearson's Composition and Analysis of Food 9th Edition 1991
Energy (By Calculation)	0%	Pearson's Composition and Analysis of Food 9th Edition 1991
Carbohydrates (By Difference)	0%	Pearson's Composition and Analysis of Food 9th Edition 1991

Pesticides Characteristics

Malathion	Max. 0.0001	USEPA 8141 A
2, 4-D	Max. 0.0001	
DDT	Max. 0.0001	USEPA 508 AOAC 990.06
Alachor	Max. 0.0001	USEPA 525.2, 507
Isoproturon	Max. 0.0001	USEPA 532
Aldrin/ Dieldrin	Max. 0.0001	USEPA 508
Parathion	Max. 0.0001	
Benzene hexachloride	Max. 0.0001	
Fenitrothion	Max. 0.0001	
Carbaryl	Max. 0.0001	
Aldicarb	Max. 0.0001	
Methyl parathion	Max. 0.0001	USEPA 8141 A
Carbofuran	Max. 0.0001	
Dimethoate	Max. 0.0001	
Phosalone	Max. 0.0001	
Ethion	Max. 0.0001	
Dichlorvos Max. 0.0001		
Chlorpyrifos	Max. 0.0001	
Fenthion	Max. 0.0001	
Phosphamidon	Max. 0.0001	
Endosulfan	Max. 0.0001	
Fenvalerate	Max. 0.0001	
Permethrin	Max. 0.0001	
Atrazine	Max. 0.0001	USEPA 525.2, 507
Simazine	Max. 0.0001	
Captafol	Max. 0.0001	
Acephate	Max. 0.0001	
Dithiocarbamates	Max. 0.0001	
Metalaxyd	Max. 0.0001	
Fosetyl aluminium	Max. 0.0001	
Lindane	Max. 0.0001	USEPA 508
Residue - Total Pesticide Residue	0.0005	

Radioactivity

Gross Alpha Activity (Bq/l)	0.1
Gross Beta Activity (Bq/l)	1

Packing Material overall Migration

Packing Colour migration	10 mg/l,Max
Packing Container	Conformity to IS 15410

17. Draft Standard for Flavoured water (Non- sweetened) Food Additive

Food Additive, Indian Food Code 14.1.4.3 Level in ppm *#/**/#	Recommended Max	USFDA FDA: 21 CFR GRAS
Amla - <i>Phyllanthus emblica</i>	14	N/A
Black Pepper = <i>Piper nigrum</i> L.	15	CFR.21 §182.10; CFR.21 §182.20
Centenella asiatica extract	25	N/A
Camomile Flower Extract = <i>Anthemis nobilis</i> L.	4	CFR.21 §182.20
Cardamom Oleoresin	15	CFR.21 §182.20; CFR.21 §182.10
Cinnamon Bark Extract	20	CFR.21 §182.20
Clove	15	CFR.21 §184.1257; CFR.21 §184.1259
Corainder = <i>Coriandrum sativum</i> L.	25	CFR.21 §182.10; CFR.21 §182.20
cucumber = <i>cucumis sativus</i> fruit extract	50	CFR.21 §182.20
Cumin = <i>Cuminum cyminum</i> L.	20	CFR.21 §182.10; CFR.21 §182.20
DILL = <i>Anethum graveolens</i> Extract	3	CFR.21 §182.20
Fennel = <i>Foeniculum vulgare</i>	25	CFR.21 §182.10; CFR.21 §182.20
Fenugreek = <i>trigonella foenum-graecum</i> l. extract	50	CFR.21 §182.10; CFR.21 §182.20
Ginger (Zingiber Officinale)	20	CFR.21 §182.10; CFR.21 §182.20
Camellia sinensis Extract	75	CFR.21 §182.20
gudhal = <i>Hibiscus</i>	3	CFR.21 §182.10; CFR.21 §182.20
Hops Extracts (flavour)	4	CFR.21 §182.20
Jasmine = <i>Jasminum officinale</i> Extract	3	CFR.21 §182.20
kokum fruit = <i>garcinia indica</i>	25	CFR.21 §182.20
Lavender = <i>Lavendula officinalis</i> Chaix	3	CFR.21 §182.20
Lemongrass Extract	15	CFR.21 §182.20
Lemons and limes Extract	20	CFR.21 §182.14
Licorice or <i>glycrrhiza</i> (flavour)	25	CFR.21 §182.20
Nutmeg Extract	15	CFR.21 §182.20
Orange, Sweet	25	CFR.21 §182.20
pudina = <i>Mentha arvensis</i>	25	CFR.21 §182.40
Rajnigandha = <i>Polianthes tuberosa</i>	4	CFR.21 §182.20
Rose Water Extract	3	CFR.21 §182.20
Sarsaparilla = <i>Smilax aristolochiifolia</i> Extract	15	CFR.21 §182.20; CFR.21 §182.40
Spearmint = <i>Mentha spicata</i>	15	CFR.21 §182.20
Star Anise = <i>Illicium verum</i> Extract	10	CFR.21 §182.20; CFR.21 §182.40
Vanilla = <i>Vanilla planifolia</i>	25	CFR.21 §182.50
Vetiver Oleoresin	15	CFR.21 §182.20
Withania somnifera = <i>ashwagandha</i>	25	N/A

Indirect GRAS food additive used in Flavoured water 14.1.1 Codex GSFA /GMP used signal or combined

Indirect GRAS food additive used in Flavoured water. Permitted food additive substances as Carryover in Natural (Nature-Identical) Flavors extract preparation only as 14.1.1 Codex GSFA /GMP

18. Guidelines and codes of practice of other international authority regarding Permitted food additive substances in %

- 18.1 # Recommended Max Level of Flavor Concentrates to be used in **flavoured water (unsweetened)** in % Suggested by FSSAI (0.05%) w/w = 500 ppm
- 18.2 Labelling of Prepackaged Foods (CODEX STAN 1-1985) Sec 4.2.3.1 Spice / Herbs extracts not exceeding 2% ww (Codex (2%)w/w = 2000 ppm as per Codex GSFA GMP)
- 18.3 USFDA Certain other spices, seasonings, essential oils, oleoresins, and natural extracts that are generally recognized as safe for their intended use, within the meaning of section 409 of the Act,

19. Good hygienic practices for Flavoured water industry Version 1.

GOOD HYGIENIC PRACTICES FOR FLAVOURED WATER PROCESSING PLANT VERSION.1

- 19.1 FIELD OF APPLICATION: The hygienic practices cover the appropriate general techniques for collecting drinking water, its treatment, bottling, packaging, storage, transport, distribution and sale for direct consumption, so as to guarantee a safe, healthy and wholesome, product.
- 19.2. HYGIENE PROCEDURES FOR COLLECTION OF DRINKING WATER
Source:- Well Water, Borewell Water, Municipal (Pipe) Supply, Sea Water (used after de mineralisation) Testing :- Quality of water samples from source water should be tested in FSSAI approved labs or NABLs and the water sample must be safe for human consumption.
- 19.3 Collection:- In the case of collection of water intended for processing from ground water sources, it should be ensured that it is Free from pollution, whether caused by natural occurrence or actions of human or neglect or ill-will.
- 19.4 If water to be processed for drinking, obtained from any other potable source it should be protected from its being contaminated.

- 19.5 The firms using waters from drinking water systems should ensure that it meets the requirements of the quality standard.
- 19.6 Materials:- The pipes, pumps or other required devices coming into contact with water and used for its collection should be made of such material that they do not change the quality of water rendering it unfit.

20 PROTECTIVE MEASURES

- 20.1 All Possible precautions should be taken within the protected perimeter to avoid any pollution of, or external influence on, the quality of the ground or surface water. Preventive measures should be taken for disposal of liquid, solid or gaseous waste that could pollute the ground or surface water. Drinking water sources should not be in the path of potential source of underground contamination.
- 20.2 Protection of the Area of Origin - The immediate surroundings of the extraction or collection area should be protected by limiting access to authorized persons only. Well heads and spring outflows should be protected by a suitable structure to prevent entry by un-authorised individuals, pests and other animals, birds, sources of extraneous contamination.

21. TRANSPORT OF DRINKING WATER

- 21.1 Means of Transport, Piping and Reservoirs - Any Vehicle, piping or reservoir used in transport of water from its source to the bottling facilities, should be made of inert material such as food grade plastic, ceramic and stainless steel, which prevent any deterioration, be it by water, handling, servicing or by disinfection and it should allow easy cleaning.

21.2 Maintenance of Vehicles and Reservoirs:- Any vehicle or reservoir should be properly cleaned and, if necessary, disinfected and kept in good condition to the extent that it will not present any danger of contamination to drinking water and of deterioration of its quality.

22. ESTABLISHMENT FOR PROCESSING OF DRINKING WATER - DESIGN AND FACILITIES

22.1 Location - Establishments should be located in areas which are free from objectionable odors, smoke, dust or other contaminants and are not subject to flooding.

22.2 Roadways and Areas Used by Wheeled Traffic - Such roadways and areas serving the establishment which are within its boundaries or in its immediate vicinity should have a hard paved or Black Topped surface suitable for wheeled traffic. There should be adequate drainage and provision should be made for protection of the extraction area.

22.3 Buildings and Facilities:-

A Type of Construction Buildings and facilities should be of sound construction and maintained.

B Disposition of Holding Facilities:-Rooms for storing or Processing of water and areas for cleaning of containers to be reused should be Separate from the bottling areas to prevent the product from being contaminated. Raw materials and packaging materials and any other materials should be stored apart from product.

C Adequate working space should be provided to allow for satisfactory performance of all operations.

D The design should be such as to permit easy and adequate cleaning and to facilitate proper supervision of hygiene for drinking water.

- E The buildings and facilities should be designed to provide separation by partition, location or other effective means between those operations which may cause cross-contamination by partition, location or other effective means between those operations which may cause cross-contamination.
- F Buildings and facilities should be designed to facilitate hygienic operations by means of a regulated flow in the process from the arrival of the drinking water at the premises to the finished product, and should provide for appropriate conditions for the process and the product.

23. Drinking Water Handling, Storing and Bottling Areas:

Floors where appropriate, should be of water-proof, non-absorbent, washable, non-slippery and made of non-toxic materials, without crevices, and should be easy to clean and disinfect. Where appropriate, floors should have sufficient slope for liquids to drain to trapped outlet.

- A Walls:- Where appropriate, should be of water proof, non-absorbent, washable and non-toxic materials and should be light colored. Up to a height appropriate for the operation they should be smooth and without crevices, and should be easy to clean and disinfect. Where appropriate, angles between walls, between walls and floors, and between walls and ceilings should be sealed and smoothen to facilitate cleaning
- B Ceilings - Should be so designed, constructed and finished as to prevent the accumulation of dirt and minimize condensation, mould growth and flaking, and should be easy to clean.
- C Windows - Windows and other openings should be so constructed as to avoid accumulation of dirt and those which open should be fitted with screens. Screens should be easily movable for cleaning and kept in good repair. Internal window sills should be sloped to prevent use as shelves.

- D Doors:- Should have smooth, non-absorbent surfaces and, where appropriate, be self-closing and close fitting type.
- E Stairs:- lift cages and auxiliary structures Platforms, ladders, chutes, should be so situated and constructed as not to cause contamination to drinking water. Chutes should be constructed with provision of inspection and cleaning hatches.
- F Piping:- Piping for drinking water lines should be independent of non-potable water. Non potable water pipes should have a different colour from potable water pipes for easy identification.
- G In drinking water handling areas all overhead structures and fittings ensure, mould growth and flaking. They should be easy to clean. should be installed in such a manner as to avoid contamination directly or indirectly of drinking water and raw materials by condensation and drip, and should not hamper cleaning operations. They should be insulated where appropriate and should be designed and finished as to prevent the accumulation of dirt and to minimize condensation, mould growth and flaking. They should be easy to clean.
- H Living quarters, toilets should be completely separated and should not open directly into Source /product water handling areas.
- I Where appropriate, establishments should be so designed that access can be controlled. The use of material which cannot be adequately cleaned and disinfected, such as wood , should be avoided unless its use would not be a source of contamination.
- J Canalisation Drainage Lines:- Canalisation and drainage and used water lines should be built and maintained in such a manner as not to present any risk whatsoever of polluting the underground water source.

K Fuel Storage Area:- Any storage area or tank for the storing of fuels such as coal or hydrocarbons should be designed, protected, controlled and maintained in such a manner as not to present a risk of pollution during the storage and manipulation of these fuels.

24. HYGIENIC FACILITIES

24.1 Water Supply

A Ample supply of potable water under adequate pressure and of suitable temperature should be available with adequate facilities for its storage, where necessary, and distribution with adequate protection against contamination. The potable water should conform to the standard for drinking water.

B Potable water, non potable water for steam production or for refrigeration or for any other use should be carried in separate line with no cross connection between. It would be desirable that these lines be identified by different colors.

C Effluent and Waste Disposal Establishments should have an efficient effluent and waste disposal system which should at all times be maintained in good order and repair. All effluent lines (including sewer systems) should be large enough to carry the full loads and should be so constructed as to avoid contamination of potable water supplies.

D Changing Facilities and Toilets Adequate, suitable and conveniently located: changing facilities and toilets should be provided in all establishments. Toilets should be so designed as to ensure hygienic removal of waste matter.

E These areas should be well lighted, ventilated and should not open directly on to product water handling areas. Hand washing facilities with warm or hot and cold water, a suitable hand-cleaning preparation, and suitable hygienic means of drying hands, should be provided adjacent to toilets and in such a position that the employee will have to use them when returning to the processing area.

F Where hot and cold water are available mixing taps should be provided. Where paper towels are used, a sufficient number of dispensers and receptacles should be provided near each washing facility. Care should be taken that these receptacles for used paper towels are regularly emptied. Taps of a non-hand operable type are desirable. Notices should be posted directing personnel to wash their hands after using the toilet.

G Hand Washing Facilities in Processing Areas :- Adequate and conveniently located facilities for hand washing and drying should be provided wherever the process demands. Where appropriate, facilities for hand disinfection should also be provided.

H Warm or hot and cold water should be available and taps for mixing the two should be provided. There should be suitable hygienic means of drying hands. Where paper towels are used, a sufficient number of dispensers and receptacles should be provided adjacent to each washing facility. Taps of a non-hand operable type are desirable. The facilities should be furnished with properly trapped waste pipes leading to drains.

25 Disinfection Facilities Where appropriate:- adequate facilities for cleaning and disinfection of equipment should be provided. These facilities should be constructed of corrosion resistant materials, capable of being easily cleaned, and should be fitted with suitable means of supplying hot and cold water in sufficient quantities.

26 Lighting:- Adequate lighting should be provided throughout the establishment. Where appropriate, the lighting should not alter colors and the intensity should not be less than: 540 lux (50 foot candles) at d protected to prevent contamination of product water in case of breakage. (10 foot candles) in other areas. Suspended light bulbs and fixtures in any stage of production should be of a safer type and protected to prevent contamination of product water in case of breakage.

27 Ventilation:- Adequate ventilation should be provided to prevent excessive heat, steam condensation and dust and to remove contaminated air. The direction of the air flow Ventilation openings should be provided with a screen or other protecting enclosure of non-corrodible material. Screens should be easily removable for cleaning.

27.1 Facilities for storage of waste and Inedible Material Facilities should be provided for the storage of waste and inedible material prior to removal from the establishment. These facilities should be designed to prevent access to waste or inedible material by pests and to avoid contamination of product water

28. EQUIPMENT AND UTENSILS

28.1 Materials:- All equipment and utensils used in product water handling areas and which may contact the product water should be made of material which does not transmit toxic substances, odour or taste, is non-absorbent, is resistant to corrosion and is capable of withstand repeated cleaning and disinfection.

28.2 Surface should be smooth and free from pits and crevices. The use of wood and other materials which cannot be adequately cleaned and disinfected should be avoided except when their use would not be a source of contamination.

28.3 Hygienic Design, Construction and Installation All equipment and utensils should be so designed and constructed as to prevent hazards and permit easy and thorough cleaning and disinfection.

29. ESTABLISHMENT

29.1 Maintenance:- The buildings, equipment, utensils and all other physical facilities of the establishment, including drains, should be maintained in good repair and in an orderly condition.

29.2 Cleaning and Disinfection to prevent contamination of product water, all equipment and utensils should be cleaned as frequently as necessary and disinfected whenever circumstances demand.

29.3 Adequate precautions should be taken to prevent product water from being contaminated during cleaning or disinfection of rooms, equipment or utensils, by wash water and detergents or by disinfection and their solutions. Detergents and disinfectants should be suitable for the purpose intended. Any residues of these agents on a surface which may come in contact with product water should be removed by thorough rinsing with water, before the area or equipment is again used for handling product water.

29.4 Either immediately after cessation of work for the day or at such other times as may be appropriate, floors, including drains, auxiliary structures and walls of water handling areas should be thoroughly cleaned.

30. Hygiene Control Program:-

30.1 A permanent cleaning and disinfection schedule should be drawn up for establishment to ensure that all areas are appropriately cleaned and that critical areas, equipment and material are designated for special attention.

30.2 An individual, who should preferably be a permanent member of the staff of the establishment and whose duties should be independent of production should be appointed to be responsible for the cleanliness of the establishment.

30.3 He should have a thorough understanding of the significance of contamination and the hazards involved. All cleaning personnel should be well-trained in cleaning techniques.

30.4 Storage and Disposal of Waste material should be handled in such a manner as to avoid contamination of product water. Care should be taken to prevent access to waste by pests. Waste should be removed from the water handling and other working areas as often as necessary.

30.5 Immediately after disposal of the waste, receptacles used for storage and any equipment which has come into contact with the waste should be cleaned and disinfected. The waste storage area should also be cleaned and disinfected.

30.6 Exclusion of Animals that are uncontrolled or that could be a hazard to health should be excluded from establishments.

31. Pest Control

31.1 There should be an effective and continuous program for the control of pests. Establishments and surrounding areas should be regularly examined for evidence of infestation.

31.2 If pests gain entry into the establishment, eradication measures should be instituted. Control measures involving treatment with chemical, physical or biological agents should only be undertaken by direct supervision of personnel who have a thorough knowledge of the potential hazards to health resulting from the use of these agents, including those hazards, which may arise from residues.

31.3 Pesticides should only be used as a precautionary measure. Before pesticides are applied, care should be taken to safeguard product water, equipment and utensils from contamination. After application contaminated equipment and utensils should be thoroughly cleaned to remove residues prior to being used again.

32. Storage of Hazardous Substances

32.1 Pesticides or other substances which may present a hazard to health should be suitably labeled with a warning about their toxicity and use. They should be stored in locked rooms or cabinets, and dispensed and handled only by authorized and properly trained personnel or by persons under strict supervision of trained personnel. Extreme care should be taken to avoid contamination.

32.2 Except when necessary for hygienic or processing purpose, no substance which could contaminate product water should be used or stored in product water handling areas.

Personal Effects and Clothing:- Personnel effects and clothing should not be deposited in product water handling areas.

33. PERSONNEL HYGIENE AND HEALTH REQUIREMENTS

33.1 Hygiene of Water-based beverages handlers

- (1) A Water-based beverages handler must, when engaging in any Water-based beverages handling operation –
 - (a) Take all practicable measures to ensure his or her body, anything from his or her body, and anything he or she is wearing does not contaminate Water-based beverages or surfaces likely to come into contact with Water-based beverages;
 - (b) Take all practicable measures to prevent unnecessary contact with ready-to drink Water-based beverages;
 - (c) Ensure outer clothing is of a level of cleanliness that is appropriate for the handling of Water-based beverages that is being conducted;
 - (d) Only use on exposed parts of his or her body bandages and dressings that are completely covered with a waterproofed covering;
 - (e) Not drink over unprotected Water-based beverages or not to eat on surfaces likely to come into contact with Water-based beverages;
 - (f) Not to sneeze, blow or cough over unprotected Water-based beverages or surfaces likely to come into contact with Water-based beverages;
 - (g) Not spit, smoke or use tobacco or similar preparations like Chewing gum, pan masala, Suparie, in areas where Water-based beverages is handled and
 - (h) Not to urinate or defecate except in a toilet.

- (2)** A Water-based beverages handler must wash his or her hands in accordance with sub clause (4)
 - (a) immediately before working with ready-to-drink Water-based beverages after handling raw Water-based beverages; and
 - (b) Immediately after using the toilet.
- (3)** A Water-based beverages handler must, when engaging in a Water-based beverages handling operation that involves unprotected Water-based beverages or surfaces likely to come into contact with Water-based beverages, wash his or her hands in accordance with sub clause (4)
 - (a) Before commencing or re-commencing handling Water-based beverages;
 - (b) Immediately after smoking, coughing, sneezing, using a handkerchief or disposable tissue, eating, drinking or using tobacco or similar substances; and
 - (c) After touching his or her hair, scalp or a body opening.
- (4)** A Water-based beverages handler must, whenever washing his or her hands –
 - (a) use the hand washing facilities provided;
 - (b) Thoroughly clean his or her hands using soap or other effective means, and warm running water; and
 - (c) Thoroughly dry his or her hands on a single use towel or in another way that is not likely to transfer pathogenic micro-organisms to the hands.

(5) A Water-based beverages handler who handles Water-based beverages at temporary Water-based beverages premises does not have to clean his or her hands with warm running water, or comply with paragraph (4)(c), if the appropriate enforcement agency has provided the Water-based beverages business operating from the temporary Water-based beverages premises with approval in writing for this purpose.

34. **Hygiene Training:-** Managers of establishments should arrange for adequate and continuous training of all water handlers in hygienic and in personal hygiene so that they understand the precautions necessary to prevent contamination of product water.

35. **Medical Examination:-** Persons who come into contact with product water in the course of their work should have a medical examination prior to employment if the official agency having jurisdiction, acting on medical advice, considers that this is necessary, whether because of epidemiological considerations or the medical history of the protective water handler. Medical examination of water handlers should be periodically carried out and when clinically or epidemiologically indicated.

36. **Communicable Diseases:-** The management should take care to ensure that no person, whether known or suspected to be suffering from, or to be a carrier of a disease likely to be transmitted or afflicted with infected wounds, skin infections, sores or diarrhea, is permitted to work in any product water handling area in any capacity in which there is any likelihood of such a person directly or indirectly contaminating product water with pathogenic micro-organisms. Any person so affected should immediately report to the management.

37. **Injuries:-** Any person who has a cut or wound should not continue to handle product water or contact surfaces until the injury is completely protected with a waterproof covering which is firmly secured, and which is conspicuous in color. Adequate first-aid facilities should be provided for this purpose.

38. **Washing of Hands:-** every person, while on duty in a product water handling area, should wash the hands frequently and thoroughly with a suitable hand cleaning preparation under running warm water. Hands should always be washed before commencing work, immediately after using the toilet, after handling contaminated material and whenever else necessary. After handling any material which might be capable of transmitting disease, hands should be washed and disinfected immediately. Notices requiring hand-washing should be displayed. There should be adequate supervision to ensure compliance with this requirement.
39. **Personal Cleanliness:-** Every Person engaged in a product water handling area should maintain a high degree of personal cleanliness while on duty, and should, at all times while so engaged, wear suitable protective clothing including head covering and footwear, all of which should be cleanable, unless designed to be disposed off and should be maintained in a clean condition consistent with the nature of the work in which the person is engaged. Aprons and similar items should not be washed on the floor. When product water is manipulated by hand, any jewellery that cannot be adequately disinfected should be removed from the hands. Personnel should not wear any insecure jewellery when engaged in handling product water
40. **Personal Behavior:-** Any Behavior which could result in contamination product water, such as eating, use of tobacco, chewing (for example gum, sticks, betel nuts, etc) or hygienic practices such as spitting, should be prohibited in drinking water handling areas.
41. **Visitors:-** Precautions should be taken to prevent visitors as far as possible from visiting the product water handling areas, If unavoidable, the visitors should observe the provisions of 23.H and 24 B.

42. Supervision Responsible for ensuring compliance by all personnel with all requirements of 6.1 to 6.8 and the responsibility should be specifically allocated competent supervisory personnel.

43. ESTABLISHMENT: HYGIENIC PROCESSING REQUIREMENTS

43.1 Raw Material Requirements to guarantee a good and stable quality of drinking water, the quality criteria should be monitored regularly.

A Should there be a perceptible lacking in meeting the requirements, necessary corrective measures are immediately to be taken.

B Treatment The treatment may include decantation, filtration, combination filtration (for example membrane filters, depth filters, cartridges filters, and activated carbon), demineralization, reverse osmosis, aeration and disinfection.

C Processing should be supervised by technically competent personnel.

D All steps in the production process, including packaging, should be performed without unnecessary delay and under conditions which will prevent the possibility of contamination, deterioration, or the growth of pathogenic and spoilage micro-organisms.

E Rough treatment of containers should be avoided to prevent the possibility of contamination of the processed product.

F Treatments are necessary controls and should be such as to protect against contamination or development of a public health hazard and against deterioration within the limits of good commercial practice.

44. Packaging Material and Containers:- All packaging material should be stored in a clean and hygienic manner. The material should be appropriate for the product to be packed and for the expected conditions of storage and should not transmit to the product objectionable substances beyond the limits specified. The packaging material should be sound and should provide appropriate protection from contamination. Only packaging material required for immediate use should be kept in the packing or filling area.

44.1 Product containers should not have been used for any purpose that may lead to contamination of the product. In case of new containers if there is a possibility that they have been contaminated, should be cleaned and disinfected. When chemicals used for this purpose, the container should be rinsed. Containers should be well drained after rinsing. Used and unused containers should be inspected immediately before filling.

45. Filling and Sealing of Containers:- Packaging should be done under conditions that preclude the introduction of contaminates in the product.

45.1 The methods, equipment and material used for sealing should guarantee a tight and impervious sealing and should not damage the containers nor deteriorate the physical, chemical, microbiological and organoleptic qualities of product water.

45.2 Multiservice refills should be washed, rinsed and sanitised before using. Chemical sanitizers should be removed as with product specification.

46. Packaging of containers:- The packaging of containers should protect the later from contamination and damage and allow appropriate handling and storing.

47. **Lot Identification:-** Each container shall be permanently marked with code to identify the producing factory and the lot. A lot is quantity of Herbal water produced under identical conditions, all packages of which should bear a lot number that identifies the production during a particular time, interval, and usually from a particular 'processing line' or other processing unit.
48. **Processing and Production Records:-** Permanent, legible and dated records of pertinent processing and production details should be kept concerning each lot. These records should be retained for a period that exceeds the shelf life of the product or longer if required.
49. **Storage and Transport of the End-Product:** The end-product should be stored and transported under such conditions as will preclude contamination with and/or proliferation of micro-organisms and protect against deterioration of the product or damage to the container. During storage, periodic inspection of the end-product should take place to ensure that only Flavoured water which is fit for human consumption is dispatched and that the end-product specification are complied with.
50. **Food Additive (Flavor) extracts storage and mixing:-** (Flavor) extracts should be kept safely, in a cool place away from sunlight in a tight container when not used. (Flavor) mixing should be done in a separate protected area by a qualified person. Area and equipments should be clean and should be sanitized using appropriate methods.



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